

## **REMARKS**

Claims 1, 2, 4, and 15-17 were pending at the time of the mailing of the final Office Action. A Response after Final Office Action was submitted on 19 April 2010. An Advisory Action was issued on 17 May 2010, maintaining the rejections of the claims. By this amendment, claims 1, 4 and 16 have been amended. New claims 18-24 have been added. Claims 3 and 5-14 were previously cancelled.

In the Office Action of 19 February 2010, claims 1, 2, 4, and 15 were rejected under 35 U.S.C. § 102(e), as being anticipated by U.S. Patent Pub. No. US 2003/0083646 to Sirhan et al. (hereinafter “Sirhan”). Under 35 U.S.C. § 103(a), claims 16-17 were rejected as being obvious over Sirhan in view of U.S. Pat. No. 5,972,027 to Johnson (hereinafter “Johnson”). The rejections were maintained in the Advisory Action issued 17 May 2010.

Claims 1, 4 and 16 have been amended herein. Support for the amended and added claims may be found in the specification at paragraphs 0057 and 0058, which describe the embodiment shown in Fig. 5, with reference to characteristics held in common with the embodiment of Fig. 4. Claim 1 now recites a stent which includes at least three pharmaceutically active substances, where the first and the second pharmaceutically active substances are applied to the first polymer carrier, and the third pharmaceutically active substance is integrated into the second polymer carrier. Concentrations of the first and the second pharmaceutically active substances continuously change over the length of the stent. The second polymer carrier exhibits a more rapid degradation behavior than the first polymer carrier and, thus, releases the third pharmaceutically active substance more rapidly and at a higher dose than the first and second

pharmaceutically active substances applied to the first polymer carrier. Neither Sirhan nor Johnson teach or suggest such features.

As stated previously, Sirhan was cited in the final Office Action as providing a stent with a coating system comprising one or more polymer carriers and at least one pharmaceutically active substance, wherein the elution of the pharmaceutically active substance varies in the longitudinal direction of the stent. However, Sirhan does not provide as stent as recited in claim 1. Sirhan provides “areas (e.g., distal and proximal ends of the device) having variable thickness of both the source and the rate-controlling element to allow for slower or faster release” (Paragraph 34) and variable delivery of a therapeutic substance (Paragraph 135). Paragraphs 40 and 45-46 were indicated to provide that degradation behavior of the carrier can serve to differentiate the local elution characteristics. However, Sirhan does not teach or suggest a degradation and elution behavior as recited in claim 1.

Sirhan provides a fundamentally different technique for elution of a pharmaceutically active substance than the present invention. Sirhan relies on diffusion through or the degradation of a rate-controlling layer, not on the degradation behavior of the polymer carriers into which the pharmaceutically active substances are dispersed, as claimed. In one embodiment of Sirhan, an aperture is provided, through which pharmaceutical agent passes to provide localized delivery of the agent (see Fig. 9D and Paragraph 0134). No teaching or suggestion of a variation in delivery due to degradation of the carrier of the agent is observed.

Furthermore, no teaching or suggestion is observed in Sirhan of a stent which includes at least three pharmaceutically active substances, where the first and the second pharmaceutically active substances are applied to the first polymer carrier, and the third pharmaceutically active substance is integrated into the second polymer carrier. Sirhan also does not teach or suggest that

concentrations of the first and the second pharmaceutically active substances continuously change over the length of the stent. Furthermore, Sirhan does not teach or suggest that the second polymer carrier exhibits a more rapid degradation behavior than the first polymer carrier, thereby releasing the third pharmaceutically active substance more rapidly and at a higher dose than the first and second pharmaceutically active substances applied to the first polymer carrier.

To anticipate a claim, a reference must teach all elements of the claim (MPEP § 2131). Because Sirhan does not provide all the elements of claim 1, the Applicants maintain that claim 1 patentably distinguishes over Sirhan. Similarly, claims 2, 4, 15, and 22-24, which directly or indirectly depend upon and contain all the limitations of claim 1, also patentably distinguish over Sirhan. Withdrawal of the rejection under 35 U.S.C. § 102(e) is respectfully requested.

Claims 16-17 were rejected under 35 U.S.C. § 103(a) as being obvious over Sirhan in view of Johnson. To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. There must also be a reasonable expectation of success and the prior art reference or references must teach or suggest all of the claim limitations. (MPEP § 2143.)

Distinctions between Sirhan and the claimed invention, provided above, are hereby repeated with regard to the rejection under 35 U.S.C. § 103(a). As provided above, Sirhan does not teach or suggest a stent that includes at least three pharmaceutically active substances, where the first and the second pharmaceutically active substances are incorporated into the first polymer carrier, and the third pharmaceutically active substance is incorporated into the second polymer carrier, and where the concentrations of the first and the second pharmaceutically active

substances continuously change over the length of the stent, and where the second polymer carrier exhibits a more rapid degradation behavior than the first polymer carrier, releasing the third pharmaceutically active substance more rapidly and at a higher dose than the first and second pharmaceutically active substances incorporated into the first polymer carrier. Similarly, Johnson also does not teach or suggest such a stent. Johnson provides different delivery concentrations of a drug in different areas of the stent based on the porosity of the stent material itself, not on the degradation behavior of the polymer carrier of the drug. Johnson provides no indication that carrier degradation plays any role in the release of a therapeutic agent.

Johnson also does not teach or suggest a stent having a third pharmaceutically active substance incorporated into a second polymer carrier. Without such a teaching, Johnson can not teach or suggest a stent where the second polymer carrier exhibits a more rapid degradation behavior than the first polymer carrier, releasing the third pharmaceutically active substance more rapidly and at a higher dose than the first and second pharmaceutically active substances incorporated into the first polymer carrier.

Therefore, claims 16-17 patentably distinguish over Sirhan and Johnson. Likewise, claims 18-21, which directly or indirectly depend upon and contain all the limitations of claim 16, also patentably distinguish over Sirhan and Johnson. Withdrawal of the rejection of claim 16-17 under 35 U.S.C. § 103(a) is respectfully requested.

The Applicants maintain that the pending claims distinguish over the cited prior art and are in condition for allowance. The issuance of a Notice of Allowance is respectfully requested.

The final Office action was transmitted on 19 February 2010. The Examiner set a shortened statutory period for reply of 3 months from the mailing date. 19 June 2010 fell on a Saturday. Therefore, the Applicants hereby petition for a one month extension of time in making

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this response, which accompanies a Request for Continued Examination, as 21 June 2010 is the next business day following a deadline date that falls on a Saturday, Sunday, or federal holiday. The Applicants also hereby make a conditional petition for any additional extension of time for response in the event that such a petition is required. The Commissioner is authorized to charge any fee required with this paper or to credit any overpayment to Deposit Account 15-0450.

Respectfully submitted,

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